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Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition

This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

Clinical and Laboratory Standards Institute

Advancing Quality in Health Care Testing

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Abstract

Clinical and Laboratory Standards Institute document GP26-A4—*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition* provides the necessary background information and infrastructure to develop a quality management system that will meet health care quality objectives and be consistent with the quality objectives of laboratory services. This guideline provides a structure for a comprehensive, systematic approach to build quality into the laboratory's processes, assess the laboratory's performance, and implement quality improvements.

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Contents

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Foreword

The increasing awareness of the costly personal and economic impact of medical errors has focused a spotlight on quality management in health care services. In the present environment of limited resources, quality cannot be taken for granted by those who fund, receive, and provide laboratory services. Our historical perspective—of quality control and quality assurance as defining quality—needs to be superseded by a more global view of internationally accepted quality activities applied to a laboratory's scope of work.

This document revises a model, first published in 1999 by the National Committee for Clinical Laboratory Standards (NCCLS), that assists laboratories with implementation and maintenance of an effective quality management system (QMS). This model is based on and contains the QMS requirements specified by international, national, and accreditation organizations for laboratory services.[1-12]

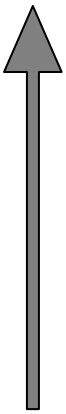
The driving force behind the original version of this guideline was the publication in 1995 of a model[13] that provided blood banks and transfusion services with a simple way to categorize all the many regulatory and accreditation requirements applicable to them, such as the Clinical Laboratory Improvement Amendments of 1988, the Food and Drug Administration Good Manufacturing Practice, The Joint Commission, the College of American Pathologists, and AABB. Persons in hospital-based blood banks and transfusion services quickly saw the applicability of the quality system model to the other medical laboratory disciplines for all the regulatory and accreditation requirements for which laboratories were accountable at the time. New requirements for laboratories, such as those in the international medical laboratory standard ISO 15189,[1] have been included in their respective portions of the model. As additional requirements are published in the future, they will continue to be incorporated into subsequent editions of this guideline.

It is true that other interpretations can be made of QMS requirements. However, this consensus document is intended as a sound, practical, and user-friendly interpretation that can be easily implemented in any laboratory. This guideline will assist an interested laboratory that seeks to obtain accreditation to relevant standards.

GP26 is a practical guide for medical laboratories that provide quality-based services. It can be used along with other quality-related documents to design the system foundation necessary to achieve total quality management.

A hierarchy defining stages of quality[14] synthesized from the concepts of acknowledged quality experts[15,16] is described in Table 1. An analogy for the stages of quality is a ladder. A laboratory can best obtain the next higher stage by mastering the preceding one, ultimately reaching the top rung. The shaded row in Table 1 indicates the level of laboratory quality for which this guideline presents a model for achievement.

Table 1. Stages of Quality. The QMS (shaded) is a major level in the health care quality hierarchy and forms the basis for this document.[14]



Stage	Activities Performed
Total Quality Management	Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction
Quality Cost Management	Measurement system for the economic aspects of the "cost of quality"
Quality Management System	**Systematic process-oriented approach to meeting quality objectives**
Quality Assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality
Quality Control	Operational process control techniques to fulfill quality requirements for regulatory compliance and accreditation[17]

An integrated QMS provides an opportunity to deliver consistent, high-quality, and cost-effective laboratory services. Where governmental and accreditation compliance apply, having a QMS will simplify this process.

Although some laboratories are working successfully at the level of a QMS (the shaded cells in Table 1), in much of the world, many laboratories are operating at or below the stage of quality assurance. The need to upgrade to a QMS approach has become evident from worldwide reports that describe medical errors in present-day health care systems,[18-20] and from reports of the cost of both good and poor quality on laboratory operations.[21] The best contribution a laboratory can make to reduce errors that can or may cause harm is to understand and document its processes, train staff to perform processes competently, identify problematic processes, and improve processes where problems exist.

The foundation of a QMS, with operations under control, provides a platform for continuous improvement and further transition up the quality hierarchy. If a laboratory implements the QMS model described in this guideline, the following outcomes are greatly enhanced:

- Ability to reduce or eliminate error
- Likelihood of meeting customer expectations
- More effective and efficient operations
- Potential for successful governmental and accreditation assessments
- Sustainable attainment of quality objectives

GP26-A4 introduces 12 building blocks of quality (referred to as quality system essentials [QSEs]) to create the management foundation needed to support the laboratory's path of workflow, from a request for a laboratory service through providing the laboratory report.

With leadership commitment to building a QMS, a platform for continuous improvement and further progress toward overall Total Quality Management is established.

Overview of Changes From GP26-A3

This document combines and replaces the previous edition of the approved guideline, GP26-A3, published in 2004, and the second edition of CLSI document HS01, also published in 2004. Several changes were made in this edition including the following:

- Reunification of the information about the QSEs with the information about the laboratory's path of workflow
- Alignment with any new or changed international, national, and accreditation requirements for laboratories since the last version of this guideline
- Additional examples of documents and forms that can be used or modified as needed for implementing a laboratory QMS

Key Words

Examination processes, path of workflow, postexamination processes, preexamination processes, quality, quality assurance, quality control, quality cost management, quality indicators, quality management, quality management system, quality system essentials, total quality management

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1 Scope

The quality management system (QMS) model described in this guideline can be used in laboratories around the world including, but not limited to:

- Medical laboratories
- Public health laboratories
- Research laboratories
- Veterinary laboratories
- Food laboratories
- Environmental laboratories

The 12 quality system essentials (QSEs) described in this guideline are universal and applicable to any size laboratory, whether simple or complex, in any laboratory discipline. This guideline is intended for use by laboratory directors, managers, supervisors, quality managers, and others responsible for implementing, maintaining, and evaluating the laboratory's QMS.

2 Introduction

The goal of an efficient and effective laboratory is to provide consistently accurate results in a timely manner with the most judicious use of resources. The complexity of laboratory services emphasizes the need for a systematic approach to provide this high level of service. A laboratory QMS is a systematic approach that describes, documents, implements, measures, and monitors the effectiveness of laboratory work operations in meeting international, national, regional, local, and organizational requirements and promotes the efficient use of resources. The ultimate objective of all this activity is to meet the expectations of the laboratory's customers.

This document is organized into five major sections. **Section 4 introduces a model for a laboratory QMS that is based on, includes, and categorizes the QMS requirements specified by international, national, and accreditation organizations for laboratory services.**[1-12] The model was derived by sorting the individual reference requirements into groups of like kind—ie, identifying all the requirements for a subject such as laboratory equipment or personnel and arranging them in the sequential order of how they occur in the laboratory. The resulting groups of requirements were recognized as fundamental building blocks of quality and were given the title of QSEs. See the "Additional important note" in Section 3.1.

Section 5 further describes the 12 QSEs and discusses the key components of each, as determined from the referenced requirements. Information is provided about laboratory processes that ensure work operations are functioning as intended to meet customer, international, national, accreditation, local, and organizational requirements, and support for the highest level of service.

Section 6 describes the laboratory's path of workflow—defined as the sequential processes in laboratory activities that transform a request for service into laboratory information. Each laboratory—whether large and complex or of narrower scope—needs to understand how work flows through it so that processes can be designed and procedures documented that will build the required level of quality into laboratory work (ie, meet the requirements) and reduce the potential for errors that could cause harm or waste resources. This guideline includes specific laboratory examples.